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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/811,508	03/26/2004	Xing Cheng	26-003820US	8613

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EXAMINER	
CHEN, STACY BROWN	
ART UNIT	**PAPER NUMBER**
1648	

DATE MAILED: 06/26/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/811,508	CHENG ET AL.	
	Examiner	Art Unit	
	Stacy B. Chen	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 April 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,4,6,10-12,14-16,19,20,35,39,46-48,53,60 and 66-73* is/are pending in the application.

4a) Of the above claim(s) *35,39,46-48,53,60 and 66* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,4,6,10-12,14-16,19,20 and 67-71* is/are rejected.

7)☒ Claim(s) *72 and 73* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *26 March 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Applicant's amendment and response filed April 11, 2006 is acknowleged and entered. Claims 1, 2, 4, 6, 10-12, 14-16, 19, 20, 35, 39, 46-48, 53, 60 and 66-73 are pending. Claims 35, 39, 46-48, 53, 60 and 66 are withdrawn from consideration being drawn to non-elected subject matter. Claims 1, 2, 4, 6, 10-12, 14-16, 19, 20 and 67-73 are under examination with respect to SEQ ID NO: 1, 9 and 10, respectively.

The following objections and rejections are either moot or withdrawn:

- The objection to the declaration is moot in view of the substitute declaration filed April 11, 2006.
- The objection to the drawings for depicting DNA sequences that are not properly identified by a SEQ ID NO, is moot in view of the amendment to the specification filed April 11, 2006.
- The objection to claims 1, 2, 4, 6, 10, 11, 14, 16, 19, 20 and 27 is moot with respect to cancelled claim 27, and withdrawn with regard to the remaining claims in view of Applicant's amendment.
- The rejection of claims 1, 2, 4, 6, 10, 14, 16, 19, 20 and 27 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, is moot with respect to cancelled claim 27, and withdrawn with regard to the remaining claims 1, 2, 4, 6, 10, 14, 16, 19 and 20 in view of the definition in paragraph [68] of the instant specification.

- The rejection of claims 1, 2, 4, 6, 10, 11, 16, 19 and 20 under 35 U.S.C. 102(b) as being anticipated by Karron *et al.* (*PNAS USA*, 1997, 94:13961-13966, "Karron") is withdrawn in view of Applicant's amendments.

Claim Rejections - 35 USC § 112

The rejection of claim 11 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, is maintained for reasons of record. The terms, "conservative" variations and "conservative" substituted amino acid residues are unclear terms. The term "conservative" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

Applicant's arguments have been carefully considered but fail to persuade. Applicant points to the specification, Table 2, at page 31. The Office has considered Table 2, as well as text surrounding the Table. The specification teaches that while Table 2 is an example of conservative mutations, there are others in the art that may be relied upon (see paragraph [0100]]). There is no clear definition of a conservative substitution in the specification, since what is defined in the specification is not complete. Therefore, the rejection is maintained for reasons of record.

Claims 1, 2, 4, 6, 10, 11, 12, 14, 15, 16, 19 and 20 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement for reasons of

record. (Previously, claims 12 and 15 were not included in this rejection. This was an oversight on the part of the examiner, as claim 12 depends from rejected claim 6, and claim 15 depends from claim 12. The written description rejection remains unchanged even with the inclusion of claims 12 and 15.) The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The claims are drawn to an isolated or recombinant nucleic acid comprising a polynucleotide sequence that is greater than 97.8% identical to SEQ ID NO: 1, or a complementary sequence thereof, wherein the polynucleotide sequence encodes an infectious, replicating respiratory syncytial virus (RSV). Another embodiment is a polynucleotide sequence encoding an amino acid sequence or unique subsequence having greater than 99.5% identity to SEQ ID NO: 9, and greater than 96.4% identity to SEQ ID NO: 10. The claims encompass a large genus of polynucleotide sequences that have not been adequately described such that one of skill in the art would be in possession of the full scope of the invention as claimed.

To provide adequate written description and evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus. The factors to be considered include disclosure of complete or partial structure, physical and/or chemical properties, functional characteristics, structure/function correlation, methods of making the claimed product, or any combination thereof.

In this case, the only factor present in the claim is a partial structure in the form of a recitation of percent identity, 97.8% identity to SEQ ID NO: 1. SEQ ID NO: 1 has 15,225 nucleotides. The number of possible variants that fall within 97.8% is so great that there is not a

representative number of variants in the specification such that Applicant was possession of the large genus of polynucleotides. There is not even identification of any particular portion of the structure that must be conserved. Even with the recitation of "wherein the polynucleotide sequence encodes an infectious, replicating respiratory syncytial virus (RSV)", the specification does not provide guidance on what core features are required to produce the virus. One of skill in the art would not know how to modify SEQ ID NO: 1 such that a sequence of any less than 100% identity would encode an infectious, replicating respiratory syncytial virus without having to experiment with different mutations at various locations along the 15,225 nucleotide sequence.

With regard to part (c) of the claims, sequences greater than 99.5% identical to SEQ ID NO: 9 and greater than 96.4% identical to SEQ ID NO: 10, are not adequately described for the same reasons. Applicant has not provided a core structure that correlates to the claimed function of being present in an infectious and replicating RSV.

Applicant's arguments have been carefully considered but fail to persuade. Applicant points to the "Written Description Requirement" published in the 1/5/01 Fed. Reg., 66(4):1099-1111. Applicant argues that the specification discloses relevant identifying characteristics (physical, chemical and/or function characteristics) that are sufficient to allow a skilled artisan to recognize that Applicant was in possession of the claimed invention. Applicant argues that what is conventional and well-known need not be disclosed in detail where the level of skill in the art is high.

In response to Applicant's arguments, the Office agrees with Applicant's assertion that, exacting detail is not necessary to meet the requirement where a specification discloses sufficient relevant identifying characteristics. As outlined above, the instant specification fails to disclose

sufficient relevant identifying characteristics such as a core structure and correlation to the claimed function (encodes an infectious, replicating RSV). Applicant's disclosure of SEQ ID NO: 2-11 as components of an infectious, replicating virus, are defined by percent identity as well. The claimed components of the sequence are not even adequately described in terms of a definite sequence. The claimed components are referred to as 99.5% and 96.4% identical to SEQ ID NO: 9 and 10, respectively. Given the variability of the claimed components, one of skill in the art is not equipped to identify the components and core structure of the claimed sequence, or the subsequences themselves.

Applicant points to genomes rg9320C4, rg9320G4, rg9320ΔG and rg9320ΔHBS (paragraph [0229]). Applicant argues that given the minimum sequence identities to SEQ ID NO: 2-11, and the well known correlation between the structure of these amino acids and their function, one of skill would be identify which regions of these proteins need to be maintained and which ones can be altered while preserving their function such that they can be incorporated into a replicating, infectious virus. Applicant also points to methods for their production (paragraph [0153]) and systems for testing the resulting recombinant viruses (see paragraph [0163]).

In response to Applicant's argument, the identification of four variants is not representative of the large genus of variants encompassed by the claims. For example, claim 1, part (c) encompasses a polynucleotide having a subsequence that encodes an amino acid having more than 99.5% identity to SEQ ID NO: 9. The polynucleotide as a whole encodes an RSV that is infectious and replicating. Given the information in the specification, one of skill in the art would have to construct the subsequence variants, and then incorporate that subsequence variant

into another polynucleotide sequence such that the entire sequence encodes an infectious and replicating RSV. This process would be reasonable if Applicant were to provide a core region within SEQ ID NO: 9 that is required such that incorporating that sequence into another sequence would result in an infectious and replicating RSV. Applicant has not provided that information. Therefore, the process of discovering the variants that have the claimed function would not be routine.

Given a core structure, polynucleotides having the deletions, insertions or substitutions along the sequences would be adequately described. While the level of skill in the art is high and the sequence of RSV is known, Applicant has not provided a functional characteristic coupled with a known or disclosed correlation between function and structure. Given a core structure correlated with a function, one of skill in the art would not need to know every detail of the claimed sequences. However, the specification has not adequately described the essential elements such that one of skill in the art would be put in possession of the full scope of the claimed invention. Accordingly, in the absence of sufficient recitation of distinguishing identifying characteristics, the specification does not provide adequate written description of the claimed genus.

Claim Rejections - 35 USC § 102

Claims 67-71 are rejected under 35 U.S.C. 102(b) as being anticipated by Karron *et al.* (*PNAS USA*, 1997, 94:13961-13966, "Karron").

The claims are drawn to an isolated or recombinant nucleic acid comprising at least one unique polynucleotide subsequence comprising at least 10 contiguous nucleotides of SEQ ID

NO: 1, or a complementary polynucleotide sequence thereof, with the proviso that the unique polynucleotide subsequence includes at least one subsequence not include in SEQ ID NO: 14-19 or a complementary polynucleotide sequence thereof. Specifically, the unique sequence is SEQ ID NO: 1; at least 100, 500 or 1000 contiguous nucleotides thereof. In another embodiment, the unique polynucleotide subsequence encodes at least 20, at least 50, at least 1000 or at least 2000 contiguous amino acid residues of SEQ ID NO: 9 or 10.

Karron teaches a polynucleotide sequence that is 99.4% identical to Applicant's SEQ ID NO: 9, encoding an M2-1 ORF, containing at least 20 contiguous amino acid residues of SEQ ID NO: 9. Karron discloses a live, cold-passaged candidate vaccine virus that lacks the SH and G proteins (abstract). Therefore, Karron's polynucleotide anticipates the claimed embodiments.

Conclusion

No claim is allowed. Claim 72 is objected to for depending from a rejected claim. Claim 73 is objected to for depending from a rejected claim and for reciting non-elected subject matter.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stacy B. Chen whose telephone number is 571-272-0896. The examiner can normally be reached on M-F (7:00-4:30). If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Stacy B. Chen 6/21/06

Stacy B. Chen
Primary Examiner
June 21, 2006